K080585

ELEKTA

JUN 11 2008

510(k) SUMMARY

Date of preparation of summary: 12th February 2008

Submitted by:
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Contact name: Mr. Patrick Hull

Trade Name:	Desktop Pro™
Common Name:	Control System, Medical Linear Accelerator
Classification Name:	Medical Linear Accelerator Accessory, IYE
Predicate Device:	Elekta Synergy® (K051932)

Product Description:

This Traditional 510(k) describes enhancements to the integral software performing the graphical interface and machine control functions for the range of medical digital linear accelerators. These enhancements enable existing control functions to be continuously varied during the delivery of radiation therapy. Thus gantry rotation and speed of rotation, multi-leaf collimator - leaf position and head rotation, back-up diaphragms and dose rate can be continuously and simultaneously varied during treatment delivery. The suffix (VMAT) is used commercially to differentiate this version of the software.

Intended Use Statement:

Desktop Pro™ (VMAT) is the interface for the Elekta range of digital medical linear accelerators and is intended to assist a licensed practitioner in the delivery of radiation to defined target volumes (e.g. lesions, arterio-venous malformations, malignant and benign tumours), whilst sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fractions, delivered as static and/or dynamic beams of radiation, in all areas of the body where such treatment is indicated.

Summary of Technological Characteristics:

Desktop Pro™ (VMAT) is an integrated digital control system, providing interface and machine control functions for the Elekta range of digital accelerators. It comprises a dedicated control cabinet on which the interface and machine control software is executed. There has been no change made to the underlying technological characteristics of the product from the predicate device.

Substantial Equivalence

The functionality for the Desktop Pro™ (VMAT) is equivalent to its predicate device the Elekta Synergy® (K051932) in safety and effectiveness. The fundamental technical characteristics are the same as those of the predicate device and differences in operation are described in the comparison chart and discussion provided elsewhere in this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2008

Mr. Patrick T M Hull
Regulatory Affairs Engineer
Elekta Limited
Linac House, Fleming Way
Crawley, West Sussex RH10 9RR
UNITED KINGDOM

Re: K080585
Trade/Device Name: Desktop Pro™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 15, 2008
Received: May 19, 2008

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080585

Device Name ..... Desktop Pro™

Indication for Use: Desktop Pro™ is the interface and control software for the Elekta range of medical digital linear accelerators and is intended to assist a licensed practitioner in the delivery of radiation to defined target volumes (e.g. lesions, arterio-venous malformations, malignant and benign tumours), whilst sparing surrounding normal tissue and critical organs from excess radiation. It is intended to be used for single or multiple fractions, delivered as static and/or dynamic beams of radiation, in all areas of the body where such treatment is indicated.

Prescription Use - YES AND/OR Over-The-Counter Use - NO

(Per 21 CFR 801.109 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080585